Applicant : Serial No. : Joseph R. Berger

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## REMARKS

Claims 59-64 are pending in the subject application.

## Rejections Under 35 U.S.C. § 102(b)

On page 2 of the June 17, 2004 Office Action, the Examiner rejected claims 59-64 under 35 U.S.C. §102(b) as allegedly being anticipated by Metcalf et al. or Karim et al. The Examiner alleged that Karim et al. teach oral administration of 10 milligrams of oxandrolone. The Examiner further alleged that Metcalf et al. teach oxadrolone administration of dosages between 2.5 and 30 milligrams. The Examiner further alleged that although these reports fail to recite skilled artisan would have seen carrier, the administration absent carriers, or excipients, as highly unlikely based on the nature of such compounds.

In response, applicant respectfully disagrees that the cited abstracts of Metcalf et al. or of Karim et al. anticipate a oxandrolone pharmaceutical composition comprising and a pharmaceutically acceptable carrier, wherein the oxandrolone is present in the composition in an amount of 7.5 milligrams or more. Both cited abstracts of Metcalf et al. and Karim et al. indicate the administered dose, but do not indicate whether the dose administered was the result of administration of one or of multiple pharmaceutical compositions.

Accordingly, applicant respectfully submits that the abstracts of Metcalf et al. or of Karim et al. do not anticipate applicant's claims 59-64 and respectfully requests that the Examiner reconsider and withdraw this rejection.

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## Rejections Under 35 U.S.C. § 103

On page 3 of the June 17, 2004 Office Action, the Examiner rejected claims 59-64 under 35 U.S.C. §103 as allegedly being unpatentable over Metcalf et al. and Karim et al. The Examiner alleges that Metcalf et al. and Karim et al. teach the claimed oxandrolone compound as old and well known in various pharmaceutical dosage forms. The Examiner alleged that this medicament is taught as useful for those therapies conventional for anabolic steroids. The Examiner alleged that claims 59-64, and the primary references, differ as to: 1) the recitation of carriers or excipients with these medicaments, and 2) administration of exactly 20 milligrams of this medicament.

In response, applicant respectfully disagrees that the cited abstracts of Metcalf et al. or of Karim et al. make obvious a pharmaceutical composition comprising oxandrolone pharmaceutically acceptable carrier, wherein the oxandrolone is present in the composition in an amount of 7.5 milligrams or more. Both cited abstracts of Metcalf et al. and Karim et al. indicate the administered dose, but do not indicate whether the dose administered was the result of administration of one or of multiple pharmaceutical compositions.

Accordingly, applicant respectfully submits that the abstracts of Metcalf et al. or of Karim et al. do not make obvious applicant's claims 59-64 and respectfully requests that the Examiner reconsider and withdraw this rejection.

No fee, other than \$1020.00 for a petition for a three-month extension of time, which the undersigned hereby authorizes the Commissioner to charge to Deposit Account No. 03-3125, is deemed necessary in connection with the filing of this Response. If any such fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

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If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

Respectfully submitted,

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